treatment administered, maintenance and production records, disposition records, necropsy records, if any, and all other pertinent records shall be included.

(Approved by the Office of Management and Budget under control number 0579–0013)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996; 66 FR 21064, Apr. 27, 2001]

§ 116.7 Test records.

Detailed records of all tests conducted on each serial and each subserial shall be maintained by the licensee. Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. Blank forms for such summaries shall be available from Animal and Plant Health Inspection Service upon request.

(Approved by the Office of Management and Budget under control number 0579–0013)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991; 61 FR 52874, Oct. 9, 1996]

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

[61 FR 52874, Oct. 9, 1996]

PART 117—ANIMALS AT LICENSED ESTABLISHMENTS

Sec.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 15499, June 13, 1973, unless otherwise noted.

§ 117.1 Applicability.

(a) All animals used in licensed establishments in the preparation or testing of biological products shall meet the regulations in this subchapter and special requirements as may be prescribed by the Administrator to prevent the preparation, sale, and distribution of worthless, contaminated, dangerous, or harmful biological products.

(b) Unless otherwise authorized or directed by the Administrator, animals used in the preparation or testing of biological products shall be admitted to and maintained at the licensed establishment and ultimately disposed of in accordance with the regulations in this part, and with the Act of August 24, 1966 (Pub. L. 89–544) as amended by the Animal Welfare Act of 1970 (Pub. L. 91–579) and the regulations in parts 1, 2, and 3 of this chapter. Personnel who supervise the care and welfare of such animals shall be qualified by education, training, and experience to carry out the regulations in this part.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§ 117.2 Animal facilities.

Animal facilities shall comply with the requirements provided in part 108 of this chapter.

§ 117.3 Admittance of animals.

(a) No animal which shows clinical signs or other evidence of disease shall be admitted to the premises of licensed establishments, except as provided in paragraphs (d) and (e) of this section. The health status of all animals offered for admission shall be determined by or under the direction of a veterinarian prior to admission. If the determination cannot be made prior to admission, the animals shall be kept separate from animals already on the premises and in a quarantine area to be provided by the licensee for this purpose